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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,958	11/01/2001	Prem Chandar	J6656(C)	6486
201	7590	06/03/2004	EXAMINER	
UNILEVER PATENT DEPARTMENT 45 RIVER ROAD EDGEWATER, NJ 07020			WELLS, LAUREN Q	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/998,958	Applicant(s) CHANDAR ET AL.	
	Examiner Lauren Q Wells	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 6-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-4, 6-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 3-4, 6-12 are pending. The Amendment filed 3/11/04, amended claim 1 and cancelled claims 2 and 5.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/11/04 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-4, 6-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) Claims 1, 3-4, and 10 are vague and indefinite, as they are confusing. If the phrase “consisting essentially of” is construed as not containing additional components that will materially affect the composition, then how can the composition of claim 1 additionally comprise an elastomer or a volatile silicone oil or a retinoid booster? Do not elastomers and volatile silicones materially affect the viscosity, form, and feel of the instant composition? Do not retinoid boosters materially affect the effectiveness of the retinoid? This is confusing.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-4, 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Habif et al. (EP 832 643) in view of Simon (6,346,256).

The instant invention is directed toward an oil-in-water emulsion consisting essentially of a retinoid solubilized in a fluid oil and a polymeric emulsifier selected from the group consisting of an amphipathic block co-polymer, a polymer containing a hydrophilic backbone modified with hydrophobic groups, and mixtures thereof.

Habif et al. disclose the stabilization of an unstable retinoid in oil-in-water emulsions for skin care compositions. Exemplified is a composition comprising 3% butylene glycol-1,3 (humectant), stearyl alcohol (fluid oil alcohol), stearic acid (crystalline fatty acid), isostearyl palmitate (fluid oil), dimethicone (volatile silicone), linoleamide (retinoid booster) and 0.29% retinol. The compositions of the invention preferably have a half-lifetime of from 20-45 days at 50 C, and the fluid oil must be capable of solubilizing, at a storage temperature (25 C), the required amount of retinol or esters thereof. See pg. 3, lines 35-pg. 4, line 57; pg. 5, lines 28-29; Example 1. The reference lacks a polymeric emulsifier

Simon teaches Pemulen TR2 (a polymer containing a hydrophilic backbone modified with hydrophobic groups) as stabilizing oil-in-water emulsions. See Col. 4, lines 4-18.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add Pemulen TR2 to the oil-in-water emulsions of Habif et al. because of the expectation of achieving a highly stable emulsion.

While the reference does not teach the half-life of the retinoid in the composition of about 70 days at 50 C or the actual amount of grams of retinoid soluble per grams of oil, the composition of the combined references must have these properties, since the combined references teach the composition of the instant invention.

It is respectfully pointed out that for the purposes of searching for and applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to comprising. If an applicant contends that additional steps or material in the prior art are excluded by the recitation of “consisting essentially of”, applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention. See MPEP 2111.03.

Response to Arguments

Applicant argues, “The present retinoid stabilization does not require crystalline (i.e., solid) fatty acid”. This argument is not persuasive. The Examiner respectfully directs Applicant to the above paragraph from the MPEP regarding the transitional phrase “consisting essentially of”. It is respectfully pointed out that the phrase “consisting essentially of” is being construed as “comprising” and that Applicant has not shown that the additional component of crystalline fatty acid would materially change the characteristic’s of Applicant’s invention.

Applicant argues, "According to the present invention, the polymeric emulsifiers serve the function of preventing water from entering the retinoid phase and vice-versa, thereby advantageously achieving retinoid stability of as high as at least about 60 to 70 days at 50 C, which is greater than that possible according to Habib et al". This argument is not persuasive, as Applicant is arguing unexpected results. The Examiner respectfully directs Applicant to the guidelines for showing unexpected results. It is applicant's burden to demonstrate unexpected results over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972).

Applicant argues, "There would be no motivation for one skilled in the art to look to Simon for stabilizing retinoids as Simon has nothing to do with retinoids. One skilled in the art with the goal of stabilizing retinoids would not be motivated to look to Simon, which discusses stabilizing emulsions". This argument is not persuasive. The compositions of Habib are directed to oil-in-water emulsions and Simon teaches that incorporating Pemulen TR2 in cosmetic oil-in-water emulsions, results in oil-in-water emulsions that are more greatly stabilized. For this reason alone, one of skill would be motivated to add the Pemulen TR2 to the emulsions of Simon. It is further respectfully pointed out that the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be

the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Again, the Examiner respectfully points out that the phrase “consisting essentially of” does not exclude the crystalline fatty acid of Habif. The Examiner respectfully suggests that Applicant providing a showing that the addition of crystalline fatty acid to the instant composition will materially affect the instant composition, or that Applicant provide sound scientific rationale, as to how the addition of crystalline fatty acid to the instant composition would materially affect the instant composition.

Furthermore, on page 36 of the instant specification, crystalline fatty acids are taught as optional ingredients!

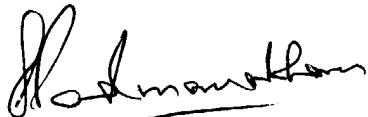
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is 571-272-0634. The examiner can normally be reached on M&R (5:30-4).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lqw


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER